PERSONALIZED MEDICINE COALITION

October 21, 2021

Margaret E. O'Kane
President
National Committee for Quality Assurance
1100 13th St., NW, Third Floor
Washington, DC 20005

Sent electronically

Re: Proposed Changes to Existing Measure for HEDIS MY 2022: Colorectal Cancer Screening

Dear Ms. O'Kane:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising more than 200 institutions across the health care spectrum, thanks the National Committee for Quality Assurance (NCQA) for the opportunity to comment on its proposed changes to the existing colorectal cancer (CRC) screening measure for the Healthcare Effectiveness Data and Information Set (HEDIS) Measurement Year (MY) 2022.[i] Given that personalized medicine rests on the assumption that linking therapeutic decision-making more closely with molecularly based diagnostic testing can improve patient care and make health systems more efficient, CRC is an important area for personalized medicine because molecularly guided testing strategies span the entire course of the disease — from screening programs that detect early-stage disease to biomarker testing that tailors treatment based on a patient's characteristics and a cancer's gene expression. The HEDIS provides important information on health plan performance and the quality of cancer care; therefore, PMC supports NCQA's proposal to revise its CRC screening measure for HEDIS MY 2022 to reflect recommendations in current clinical guidelines. Furthermore, we support NCQA's removal of its hybrid measure reporting option to allow health plans to better prepare for capturing CRC screening data and facilitate the standardized use of electronic clinical data across health systems.

Personalized medicine is an evolving field in which physicians use diagnostic tests to determine which treatments will work best for each patient or use medical interventions to alter molecular mechanisms that cause disease. By combining data from diagnostic tests with an individual's medical history, circumstances, and values, health care providers can develop targeted treatment and prevention plans with their patients.

Personalized medicine is helping to shift the patient and provider experiences away from trial-and-error treatment of late-stage diseases in favor of more streamlined approaches to disease prevention and treatment, which will lead to improved patient

outcomes, a reduction in unnecessary treatment costs, and better patient and provider satisfaction. PMC's members are leading the way in personalized medicine and recommend that patients who may benefit from this approach undergo appropriate testing and targeted treatment as soon as possible during their clinical experiences.

Statement of Neutrality

Many of PMC's members will present their own responses to NCQA. PMC's comments are designed to provide feedback so that the general concept of personalized medicine can advance, and are not intended to impact adversely the ability of individual PMC members, alone or in combination, to pursue separate comments on the proposed changes to the existing CRC screening measure for HEDIS MY 2022.

Burden of Colorectal Cancer and Need for Earlier Detection

According to the Colorectal Cancer Alliance, CRC is the third most common cancer diagnosed in the United States.[ii] The Alliance estimates that in 2021, nearly 150,000 people will be diagnosed with CRC and almost 53,000 will die from the diseases. Currently, for colon cancer, the median age of diagnosis is 68 years in men and 72 years in women. For rectal cancer, the median age at diagnosis is 63 in both men and women.[iii] Young onset CRC is on the rise, with cases under the age of 55 increasing at two percent each year.[iv]

The U.S. Preventive Services Task Force (USPSTF) stated that maximizing the total number of persons screened will have the greatest effect on reducing CRC deaths, and that offering choice in screening strategies may further this goal.[v] Nearly half of CRC cases and deaths would be preventable with improved screening.[vi] Unfortunately, the most recent data show that as many as 30 percent of eligible individuals are not up to date on CRC screening.[vii]

The survival rate for CRC has been slowly increasing due in part to improved screening and treatment options. Molecular screening tests, which are a hallmark of personalized medicine, including blood-based cancer tests, are emerging as an additional way to detect cancer early. Screening can be effective for detecting early cancers that can be more easily treated through individualized approaches. In fact, the five-year relative survival rate is as high as 90 percent for individuals whose CRC is found in the early stage and effectively treated before it has spread.[viii]

Proposed Changes to Colorectal Cancer Screening Measure

The American Cancer Society recommends certain CRC screening modalities for individuals at age 45.[ix] Colorectal cancer screening is also recommended by the USPSTF for the general population starting at age 50 and continuing until age 75. The USPSTF provided an "A" recommendation for this age group, which means that the evidence showed a substantial net benefit to screening these individuals. In May 2021, the USPSTF released an updated guideline that now recommends screening adults aged 45 – 49 because of increased incidence of CRC in this population.[x]

The existing CRC screening measure for HEDIS assesses the percentage of adults aged 50 – 75 who receive appropriate screening. While this may have been sufficient under previous clinical guidelines, it does not capture the percentage of younger adults who should now be screened under current USPSTF recommendations. We understand that reporting on these measures is often tied to fiscal and other incentives to achieve quality metrics. While measures for quality and other forms of accountability are usually derived from the same evidence as clinical guidelines, they are not always aligned.

PMC appreciates NCQA recognizing the value of earlier detection and proposing to change the CRC screening measure for HEDIS MY 2022 based on the recent USPSTF guidelines. We encourage you to proceed with adding individuals aged 45 – 49 to HEDIS MY 2022. PMC believes this change will ensure alignment between the measure and updated clinical guidelines while facilitating more rapid provider adherence to evidence-based screening recommendations. To capture accurate information on screening provided to those at greater risk for CRC, NCQA should consider ways to improve reporting on the percentage of individuals screened with inherited risk.

Likewise, PMC supports NCQA's proposal to remove its hybrid measure reporting option and establish the Electronic Clinical Data Systems (ECDS) method. The ECDS supports care-related activities, including evidence-based decision support, quality management, and outcomes reporting. Data in the ECDS are structured such that automated quality measurement queries can be consistently and reliably executed. NCQA previously added the ECDS method as a reporting option to three existing HEDIS measures: *Breast Cancer Screening*, *Colorectal Cancer Screening* and *Follow-up Care for Children Prescribed ADHD Medication*. Removing the hybrid reporting option and transitioning to ECDS could reduce the burden of manual chart review, allow health plans to better prepare for capturing CRC screening data, and facilitate the standardized use of these data across health systems to help drive improvements in the quality of care that early-stage CRC patients receive.

Conclusion

Thank you for releasing the proposed changes to HEDIS MY 2022 and for considering our comments. PMC welcomes the opportunity to serve as a resource for you in continuing to shape quality activities that support the appropriate deployment of personalized medicine. If you have any questions about the content of this letter, please contact me at 202-499-0986 or cbens@personalizedmedicinecoalition.org.

Sincerely,

Cynthia A. Bens
Senior Vice President, Public Policy

[i] National Committee for Quality Assurance. *Draft Document for HEDIS ad Hoc Public Comment.* September 30, 2021. https://www.ncqa.org/wp-content/uploads/2021/09/All-Public-Comment-Materals.pdf.
[ii] Colorectal Cancer Alliance. *Statistics and Risk Factors*. https://www.ccalliance.org/colorectal-cancer-information/statistics-risk-factors.
[iii] Colorectal Cancer Alliance. *Statistics and Risk Factors*. https://www.ccalliance.org/colorectal-cancer-information/statistics-risk-factors.
[iv] Colorectal Cancer Alliance. *Statistics and Risk Factors*. https://www.ccalliance.org/colorectal-cancer-information/statistics-risk-factors.
[v] U.S. Preventive Services Task Force. *Final Recommendation Statement: Colorectal Cancer Screening*. May 18, 2021. https://uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening#fullrecommendationstart.
[vi] Centers for Disease Control and Prevention. *Vital Signs: Colorectal Cancer*. July 2011. https://www.cdc.gov/vitalsigns/cancerscreening/colorectalcancer/index.html.
[vii] U.S. Preventive Services Task Force. *Final Recommendation Statement: Colorectal Cancer Screening*. May 18, 2021. https://uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening#fullrecommendationstart.
[viii] American Cancer Society. *Colorectal Cancer Early Detection, Diagnosis, and Staging*. January 29, 2021. http://www.cancer.org/acs/groups/cid/documents/webcontent/003170-pdf.pdf.
[ix] American Cancer Society. *Guideline for Colorectal Cancer Screening*. https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/acs-recommendations.html.
[x] U.S. Preventive Services Task Force. *Final Recommendation Statement: Colorectal Cancer Screening*. May 18, 2021. https://uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening#fullrecommendationstart.